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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,616	01/22/2002	Larry S. Barak	033072-022	7096

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EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,616	BARAK ET AL.	
	Examiner	Art Unit	
	Michael Pak, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

PART I: RESTRICTION OF GROUPS

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to modified GPCR polypeptides, classified in class 530, subclass 350.

II. Claims 18-22 and 49, drawn to nucleic acids encoding modified GPCR polypeptides, vectors comprising the nucleic acids, and host cells comprising the vectors, classified in class 435, subclass 320.1, for example.

III. Claims 23 and 25-28, drawn to methods of identifying compounds which inhibit arrestin binding to a GPCR, classified in class 436, subclass 501, for example.

IV. Claims 24 an 29-37, drawn to methods of identifying compounds that interfere with agonist-independent localization of arrestin, classified in class 435, subclass 4, for example.

V. Claims 38 and 40, drawn to compounds which inhibit arrestin binding to a GPCR, classification dependent upon structure of recited compounds.

VI. Claims 39 and 41, drawn to compounds that interfere with agonist-independent localization of arrestin, classification dependent upon structure of recited compound.

VII. Claims 42 and 43, drawn to methods of identifying a compound for GPCR antagonist or inverse agonist activity, classified in class 435, subclass 7.2, for example.

VIII. Claims 44-46, drawn to transgenic animals, classified in class 800, subclass 8.

IX. Claim 47, drawn to a method of detecting a modified GPCR in a sample using an antibody, classified in class 435, subclass 7.1.

X. Claim 48, drawn to a method of detecting a nucleic acid in a biological sample, classified in class 435, subclass 6.

XI. Claims 50-53, drawn to antibodies, classified in class 530, subclass 387.1.

XII. Claims 54 and 55, drawn to methods of inhibiting constitutive desensitization of a GPCR, classified in class 514, subclass 1, for example.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I, II, V, VI, VIII, and XI are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group I can be prepared by processes which are materially different from recombinant DNA expression of Group II, such as by chemical synthesis, or by isolation and

purification from natural sources. Additionally, the DNA of Group II can be used other than to make the protein of Group I, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group I can be used in materially different methods other than to make the antibody of Group XI, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group XI can be used to obtain the DNA of Group II, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The DNA of Group II can be used to make the transgenic animal of Group VIII; however, it can also be used in diverse methods such as recombinant production of the encoded protein, therapy, and in methods of isolating its binding partners. Finally, the compounds of Groups V and VI have unique functional features, each requiring its own search. Therefore, a search and examination of all of the claimed products in one patent application would result in an undue burden, in that each product requires its own search of the literature and sequence databases.

Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups III, IV, VII, IX, X, and XII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention III requires search and examination of methods of identifying compounds which inhibit arrestin binding to GPCRs, which is not required by any of the other groups. Invention IV requires search and examination of

methods of identifying compounds that interfere with agonist-independent localization of arrestin, which is not required by any of the other groups. Invention VIII requires search and consideration of methods of identifying compounds for GPCR antagonist or inverse agonist activity, which is not required by any of the other groups. Each of these screening assay groups recite different method steps, and require screening for compounds with different activity. Invention IX requires search and examination of method using antibodies, which is not required by any of the other groups. Invention X requires search and consideration of DNA screening methods, which is not required by any of the other groups. Finally, Invention XII requires search and consideration of methods of inhibiting desensitization of a GPCR, which involves reagents and method steps not required by any of the other groups. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions II and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used to make the encoded protein recombinantly, or in gene therapy.

Inventions XI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used therapeutically.

Inventions III and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compounds can be made synthetically.

Inventions IV and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compounds can be made synthetically.

The remaining pairs of inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case each of the invention pairs has one invention directed to a product, and the other directed to a method. In each case the product cannot be used in the method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

PART II: ELECTION OF SPECIES:

Claims 1-55 are generic to a plurality of disclosed patentably distinct species comprising different structures of the recited polypeptide receptors or arrestin. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species **(i.e., a single sequence for the recited polypeptide)**, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). **Both a group and a species must be elected in order to be fully responsive.**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, Ph.D., whose telephone number is (571) 272-0879.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ECK